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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,152	08/25/2003	Perry G. Caimi	CL2123 US NA	3625

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/648,152

Applicant(s)

CAIMI ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-34 are currently pending in this application.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 5-11, 15-22, drawn to polynucleotides, vectors, host cells, and chimeric polynucleotides classified in class 435, subclass 252.3.
- II. Claims 3-4, 12-14, 34, drawn to polypeptides having  $\alpha(1,6)$ -linked glucose oligosaccharide hydrolyzing activity, classified in class 435, subclass 210.
- III. Claims 23, 27, 28, 32, drawn to a method of making target molecules using host cells transformed with the polynucleotide encoding the polypeptide with  $\alpha(1,6)$ -linked glucose oligosaccharide hydrolyzing activity, classified in class 435, subclass 41.
- IV. Claims 24, 27, 30, 32, drawn to a method of making glycerol using host cells transformed with the polynucleotide encoding the polypeptide with  $\alpha(1,6)$ -linked glucose oligosaccharide hydrolyzing activity, classified in class 435, subclass 159.
- V. Claims 25, 27, 29, 32, drawn to a method of making propanediol using host cells transformed with the polynucleotide encoding the polypeptide with  $\alpha(1,6)$ -linked glucose oligosaccharide hydrolyzing activity, classified in class 435, subclass 156.
- VI. Claims 26, 27, 31, 32, drawn to a method of making cell mass using host cells transformed with the polynucleotide encoding the polypeptide with  $\alpha(1,6)$ -linked glucose oligosaccharide hydrolyzing activity, classified in class 435, subclass 243.

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VII. Claim 33, drawn to a method of degrading limit dextrin, classified in class 435, subclass 274.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct from each other. The polypeptide of group II, the polynucleotide of group I, each comprise amino acid sequences and nucleotide sequences which are chemically unrelated, do not require each other for practice; have separate utilities, such as use of the group I polypeptide to catalyze a esterification reaction versus the use of polynucleotide in a hybridization reaction and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions I or II and III through VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used as probes in a hybridization as opposed to its use in making host cells that can be used in the process of groups II through VII. On similar lines, the polypeptide of Group II, which is actually the final product produced by the host cell which is responsible for generation of the target molecules such as glycerol, propanediol or cell mass can be used to raise specific antibodies as opposed to its use through the host cell.

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Inventions III through VII are patentably distinct from each other. The method of making any molecule as a target molecule of group III, the method of making glycerol of group IV, the method of making propanediol of group V, the method of producing cell mass of group VI and the method of degrading limit dextrin of group VII are all unrelated as they comprise distinct steps, utilize different products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

***Election of a single sequence***

All claims are drawn to polynucleotide or polypeptide sequences and methods of using the same. The sequences claimed in this application are as follows

Polynucleotide sequences; SEQ ID NO:1, 3, 5, 16, 24, 25, 26, 27, 30, 28, 32, 34, 36, 38, 40, 42.

Polypeptide sequences; SEQ ID NO:2, 4, 6, 17, 31, 29, 33, 35, 37, 39, 41, 43.

Applicants are reminded that the above nucleotide sequences and polypeptide sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide/polypeptide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.*

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This requirement is not to be construed as a requirement for an election of species, since each nucleotide sequence is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention. Therefore the method of using each of the polynucleotide is also distinct from each other.

Therefore, along with the election of a single group, the applicant is required to elect a single sequence from the above set. Applicant is advised that the reply to this requirement to be complete must include an election of the sequence to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

### ***Species Election***

This application contains claims directed to the following patentably distinct species of the claimed invention: The distinct species claimed are the chimeric polynucleotides comprising the polynucleotide encoding a polypeptide having  $\alpha(1,6)$ -linked glucose oligosaccharide hydrolyzing activity and one of the following regulatory sequences;

1 CYCI,

2 HIS3,

3 GALI,

4 GAL10,

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5 ADH1,

6 PGK,

7 PHO5,

8 GAPDH,

9 ADC1,

10 TRP1,

11 URA3,

12 LEU2,

13 ENO,

14 TPI,

15 AOX1,

16 lac,

17 ara,

18 tet,

19 trp,

20 IPL,

21 IPR,

22 T7,

23 tac,

24 trc,

25 apr,

26 npr

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27 nos,

28 Gl.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 15, 17-22 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.



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Applicant is advised that the reply to this requirement to be complete must include an election (of claims, a sequence associated with the elected group and a species if the elected group includes claim 16) of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Rejoinder of restricted inventions***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. **Thus, to be allowable, the**

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**rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.** Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.** See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to rejoin, in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner’s supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "Manjunath N. Rao". The signature is stylized with a large, looping initial "M" and a long, sweeping horizontal stroke at the end.

Manjunath N. Rao, Ph.D.

Primary Examiner

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January 31, 2006